PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Brent Gerberding**
Application No.:	**10/063937**
Filed:	**May 28, 2002**
For:	**Polar Radiopaque Marker for Stent**
Examiner:	**Elizabeth Houston**
Group Art Unit:	**3731**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-10447-US01

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application for which claims 1, 2, 4-10, 13-18, 22-28, 34 and 35 were finally rejected in the office action dated November 14, 2007.

Claims 1, 2, 4-10, 13-18, 22-28, 34 and 35 are pending in the application.

A Notice of Appeal was filed in this case on March 10, 2008. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account 22-0350 for any other fees which may be due with this appeal.

(i) Real Party in Interest

The application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

None.

(iii) Status of Claims

Claims 1, 2, 4-10, 13-15, 26-28, 34 and 35 are pending in the application and have been twice or finally rejected. Claims 16-18 and 22-25 have been withdrawn from consideration. Claims 3, 11, 12, 19-21 and 29-33 have been canceled.

(iv) Status of Amendments

All amendments have been entered to date.

(v) Summary of Claimed Subject Matter

A summary of representative independent claims as required by 37 C.F.R. §41.37(c)(1)(v) and any dependent claims argued separately, and a non-limiting listing of locations where support may be found [bracketed citations] referring to the specification by page and line number, and to any drawing, is provided as follows:

Independent claim 1 is directed to a medical device having a longitudinal axis

including a first serpentine band and a second serpentine band adjacent thereto, each serpentine band formed of interconnected struts and having a distal end and a proximal end, each strut extending between a peak at the distal end of the serpentine band and a trough at the proximal end of the serpentine band, at least one of the struts being a special strut, each special strut having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region, the first region curving in a direction opposite to the second region relative to the longitudinal axis of the device, each special strut having a radiopaque marker between the first and second regions, each special strut having a plurality of interconnected struts adjacent the first side, the interconnected struts having curved regions which curve about the first region and a plurality of interconnected struts adjacent the second side, the interconnected struts having curved regions which curve about the second region, the first serpentine band connected to the second serpentine band by a connector which extends from one of the ends of the first serpentine band to one of the ends of the second serpentine band, at least one cover, the at least one cover on at least one region of the medical device, a plurality of the radiopaque markers marking the proximal end of the at least one region and a plurality of the radiopaque markers marking the distal end of the at least one region [par. 0010, par. 0026, par. 0027, Fig. 1a, par. 0056, par. 0057 and par. 0058, Figs. 2b-2e].

Claim 6 depends from claim 1 and is directed to an embodiment having a second cover covering a second region of the stent, another portion of the special struts located at the periphery of the second region of the stent [par. 0005 , par. 0054].

Claim 13 depends from claim 1 and is directed an embodiment wherein the radiopaque markers are in the form of plated radiopaque material, coated radiopaque material, or

painted radiopaque material [par. 4, par. 0028, par. 0045, claim 13 as filed].

Claim 14 depends from claim 1 and is directed to an embodiment wherein the radiopaque markers are in the form of swaged radiopaque material or welded radiopaque material [par. 0045].

Independent claim 26 is directed to a stent in an unexpanded state including a plurality of serpentine bands, each serpentine band having a distal end having a peak and a proximal end having a trough and formed of interconnected struts having a first side and a second side, the plurality of serpentine bands including a proximal-most serpentine band and a distal-most serpentine band and a plurality of intermediate serpentine bands between the proximal-most and distal-most serpentine bands, some of the intermediate serpentine bands including interconnected struts which are special struts, each special strut extending from the peak of the serpentine band to the trough of the serpentine band and having a radiopaque marker there between the first side and second side, circumferentially adjacent each side of each special strut are a plurality of interconnected struts, the first side and the second side of each interconnected strut of the plurality having a curved region which curves about the radiopaque marker, a first serpentine band and a second serpentine band being immediately adjacent one another and connected by a connector extending from the distal end of the first serpentine band to the proximal end of the second serpentine band, at least one cover, the at least one cover on at least one region of the medical device, a plurality of the special struts located at one end of the cover and another plurality of the special struts located at another end of the cover to mark the location of the cover [par. 10, par. 26, par. 27, Fig. 1a, par. 56, par. 57 and par. 58, Figs. 2b-2e].

(vi) Grounds of Rejection to be Reviewed on Appeal

I. Whether the examiner erred in rejecting claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. §103(a) as being obvious over Cox et al. (USPN 6,652,579) in view of Garrison et al. (USPN 6,520,984) and further in view of Erbel et al. (US 2004/0116998).

II. Whether the examiner erred in rejecting claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 under 35 U.S.C. §103(a) as being obvious over Wolinsky (USPN 6,730,116) in view of Burgermeister (USPN 6,790,227) and further in view of Erbel et al. (US Pub 200410116998).

III. Whether the examiner erred in rejecting claim 6 under 35 U.S.C. §103(a) as being obvious over Wolinsky in view of Burgermeister and further in view of Erbel et al., and further in view of Barone (USPN 6,613,078).

IV. Whether the examiner erred in rejecting claim 6 under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Garrison and further in view of Erbel as applied to claim I above, and further in view of Barone (USPN 6,613,078).

V. Whether the examiner erred in rejecting claims 13 and 14 under 35 U.S.C. 103(a) as being obvious over Cox in view of Garrison and further in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

VI. Whether the examiner erred in rejecting claims 13 and 14 under 35 U.S.C. 103(a) as being obvious over Wolinsky in view of Burgermeister and further in view of Erbel as applied to claim I above, and further in view of admitted prior art (admission).

(vii) Argument

A. Brief Summary

I. The examiner erred in rejecting claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. §103(a) as being obvious over Cox et al. (USPN 6,652,579) in view of Garrison et al. (USPN 6,520,984) and further in view of Erbel et al. (US 2004/0116998).

II. The examiner erred in rejecting claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 under 35 U.S.C. §103(a) as being obvious over Wolinsky (USPN 6,730,116) in view of Burgermeister (USPN 6,790,227) and further in view of Erbel et al. (US Pub 200410116998).

III. The examiner erred in rejecting claim 6 under 35 U.S.C. §103(a) as being obvious over Wolinsky in view of Burgermeister and further in view of Erbel et al., and further in view of Barone (USPN 6,613,078).

IV. The examiner erred in rejecting claim 6 under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Garrison and further in view of Erbel as applied to claim I above, and further in view of Barone (USPN 6,613,078).

V. The examiner erred in rejecting claims 13 and 14 under 35 U.S.C. 103(a) as being obvious over Cox in view of Garrison and further in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

VI. The examiner erred in rejecting claims 13 and 14 under 35 U.S.C. 103(a) as being obvious over Wolinsky in view of Burgermeister and further in view of Erbel as applied to claim I above, and further in view of admitted prior art (admission).

B. Detailed Argument

I. The examiner erred in rejecting claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. §103(a) as being obvious over Cox et al. (USPN 6,652,579) in view of Garrison et al. (USPN 6,520,984) and further in view of Erbel et al. (US 2004/0116998).

Independent claim 1 of the present application recites, among other features, a medical device having at least one "special strut" that extends between a peak at the distal end of the serpentine band and a trough at the proximal end of the serpentine band. Each special strut has a first side with a first region of first curvature and a second side with a second region of second curvature, the first region opposite the second region, the first region curving in a direction opposite to the second region relative and a radiopaque marker between the first and second regions, and a cover on at least one region of the medical device.

Each special strut also has a plurality of interconnected struts adjacent the first side, the interconnected struts having curved regions which curve about the first region and a plurality of interconnected struts adjacent the second side, the interconnected struts having curved regions which curve about the second region.

At least one cover is provided on at least one region of the medical device. A plurality of the radiopaque markers mark the proximal end of the at least one region and a plurality of the radiopaque markers mark the distal end of the at least one region.

Independent claim 26 is directed to a stent having, among other features, a plurality of serpentine bands, each serpentine band having a distal end having a peak and a proximal end having a trough and formed of interconnected struts having a first side and a second side, the plurality of serpentine bands including a proximal-most serpentine band and a distal-most serpentine band and a plurality of intermediate serpentine bands between the proximal-most and

distal-most serpentine bands, some of the intermediate serpentine bands including interconnected struts which are special struts, each special strut extending from the peak of the serpentine band to the trough of the serpentine band and having a radiopaque marker there between the first side and second side.

Circumferentially adjacent each side of each special strut are a plurality of interconnected struts, the first side and the second side of each interconnected strut of the plurality having a curved region which curves about the radiopaque marker.

At least one cover is provided on at least one region of the medical device. A plurality of the special struts is located at one end of the cover and another plurality of the special struts located at another end of the cover to mark the location of the cover.

1. The Garrison security ring is not a stent

The Examiner relies, in part, on substituting the marker of the Garrison security ring into the band of Cox stent. As stated in the Advisory Action dated January 22, 2008:

> …the fact that applicant's may be their own lexicographer does not detract from the fact that…the "security rings" are in fact stents…By definition a stent is "a small, expandable tube used for inserting in a blocked vessel or other part" and the security rings meet this definition.

The Examiner is mistaken in his assertion. The "security ring" of Garrison et al. is not a "stent" nor would one of ordinary skill in the art understand these terms to have equivalent meanings. A stent is not merely "a small, expandable tube used for inserting in a blocked vessel or other part". Rather, it must also be capable of maintaining the patency of the vessel in which it is inserted. The 'definition' of the Examiner is so broad that it would seemingly encompass any tubular device that is small enough to fit in a vessel. This would include, for example, a catheter.

One of ordinary skill in the art would not, however, consider a catheter *per se* to be a stent.

There is no disclosure in Garrison that the security ring is a stent – that it is capable of supporting a bodily vessel. The disclosure is limited to the security ring being used to secure a graft to a stent. Moreover, there is no teaching in Garrison of disposing a radiopaque marker within a serpentine band. Had Garrison wished to disclose such a feature, surely he would have.

One of ordinary skill in the art would simply not have looked to a security ring in designing the placement of a radiopaque marker on a stent.

Moreover, Erbel is silent on the issue of the placement of radiopaque marker within a serpentine band.

Even if, for the sake of argument only, one were to make the proposed combination of Cox, Garrison and Erbel, the proposed combination would not disclose all of the recited features of the claims as discussed below.

2. The proposed combination does not disclose all of the features of the claims

For example, the proposed combination would not disclose the plurality of interconnected struts having curved regions which curve about the first and second regions of the special strut. The Garrison marker is a small marker and it is not seen why any of the adjacent struts would have to be curved to accommodate it. This issue is accentuated given the locations of the connector shown in the Cox figures and given the separation between struts in the Cox design.

Consequently, as Cox et al. fail to suggest the invention recited in claim 1, and Garrison et al. fail to disclose a stent having a special strut located within a single serpentine band

of a stent, and Erbel is silent on this issue, the combination fails to produce a prima facie case of obviousness.

Combining the cover of Erbel et al. with Cox et al. and Garrison et al. still fails to produce the invention recited in claim 1. As mentioned above, Erbel is silent on the location of radiopaque markers within a band.

Concerning Erbel, the Final Office Action states:

> 10. It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers. Using a cover on the stent enhances the properties of the stent to cause thrombosis at the site of the aneurysm or tear while at the same time allowing blood to flow through the stent and the vasculature. Using radiopaque markers at the edge of the cover facilitates correct placement of the cover at the site of the aneurysm or tear in the body lumen. Erbel provides the motivation. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

Erbel does not, however, teach using the radiopaque markers of a stent, let alone those within special struts, or the recited special struts of a stent, to mark the ends of a cover. As stated in paragraph 90 of Erbel:

> [0090] With further reference to FIG. 3, endovascular prosthesis further comprises a first set of radiopaque markers 30 which are disposed on the distal edge of tubular wall 15. Further, a second set of radiopaque markers 35 are disposed at points along the distal edge of non-porous section 25. The use of such radiopaque markers facilitates correct placement of endovascular prosthesis 10 as will be described in more detail hereinbelow. The nature of radiopaque markings 30,35 is not particularly restricted. For example, radiopaque markers 30,35 may be made from gold or any other material which is opaque to X-ray radiation.

Fig. 3 of Erbel is reproduced below:

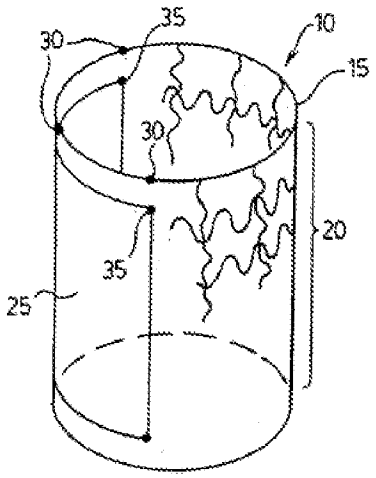

FIG. 3.

As can be seen, Erbel provides markers 35 which are disposed along the proximal/distal edges of the non-porous section. Erbel does not teach or suggest that the markers along the edge of the cover be a part of any 'special' struts of the stent, as is required by the instant claims. From Fig. 3 and the disclosure, it would appear that markers 35 form a part of the cover and not the underlying stent.

Thus, the proposed combination of references would still not disclose using special struts which include radiopaque markers to mark the ends of the cover.

Claim 26 is not obvious over this combination for at least these same reasons.

Claims 2, 4-10, 13-15, 34 and 35 depend from claim 1 and claims 27 and 28 depend from claim 26 and are not obvious over this combination for at least the reasons that claims 1 and 26 are not obvious over this combination.

II. The examiner erred in rejecting claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 under 35 U.S.C. §103(a) as being obvious over Wolinsky (USPN 6,730,116) in view of Burgermeister (USPN 6,790,227) and further in view of Erbel et al. (US Pub 200410116998).

Claim 1 has been discussed above and is directed to a medical device having,

among other features, a first serpentine band and a second serpentine band adjacent thereto, each serpentine band formed of interconnected struts and having a distal end and a proximal end, each strut extending between a peak at the distal end of the serpentine band and a trough at the proximal end of the serpentine band, at least one of the struts being a special strut.

Each special strut has a first side with a first region of first curvature and a second side with a second region of second curvature, the first region opposite the second region, the first region curving in a direction opposite to the second region relative and a radiopaque marker between the first and second regions, and a cover on at least one region of the medical device.

Each special strut has a plurality of interconnected struts adjacent the first side, the interconnected struts having curved regions which curve about the first region and a plurality of interconnected struts adjacent the second side, the interconnected struts having curved regions which curve about the second region.

Also, the first serpentine band is connected to the second serpentine band by a connector which extends from one of the ends of the first serpentine band to one of the ends of the second serpentine band.

Independent claim 26 is directed to a stent having, among other features, a plurality of serpentine bands, each serpentine band having a distal end having a peak and a proximal end having a trough and formed of interconnected struts having a first side and a second side, the plurality of serpentine bands including a proximal-most serpentine band and a distal-most serpentine band and a plurality of intermediate serpentine bands between the proximal-most and distal-most serpentine bands, some of the intermediate serpentine bands including interconnected struts which are special struts, each special strut extending from the peak of the serpentine band to the trough of the serpentine band and having a radiopaque marker between the first side and

second side.

Circumferentially adjacent each side of each special strut are a plurality of interconnected struts, the first side and the second side of each interconnected strut of the plurality having a curved region which curves about the radiopaque marker.

Claim 26 further recites a first serpentine band and a second serpentine band being immediately adjacent one another and connected by a connector extending from the distal end of the first serpentine band to the proximal end of the second serpentine band.

In the Office Action, Burgermeister has been combined with Wolinsky et al. because "Wolinsky et al. does not disclose that the serpentine bands are connected by a connector, which extends from one of the ends of the first band to one of the ends of the second band....Burgermeister discloses a stent with serpentine bands having peaks and troughs with each band connected to the adjacent band by connectors....Burgermeister states that this connector is advantageous because the overall length of the stent is maintained during expansion." See Office Action, page 6, paragraphs 13 and 14.

Applicants disagree and submit that in fact, Burgermeister would not be combined with Wolinsky et al. for this purpose because in the Background of the Invention, Wolinsky et al. disclose that Globerman, U.S. Patent No. 5,776,161, already provides a stent with connectors wherein the overall length of the stent is maintained during expansion:

> Globerman discloses an expandable stent having a small initial diameter, flexibility along its longitudinal axis prior to expansion and minimization of rigid local strain on the stent material by the presence of rotation joints which have minimal strain during stent expansion. *The stent is substantially the same length before and after expansion* and being flexible longitudinally when constrained, it is easy to deliver. However additional improvements in longitudinal flexibility in the crimped stent during delivery and scaffolding after delivery are still desired.

Wolinsky et al., col. 2, lines 52-62 (emphasis added).

Wolinsky et al. finds the Globerman stent to need improvement in"…longitudinal flexibility in the crimped stent during delivery and scaffolding after delivery…." See col. 2, lines 59-62.

In fact, because Wolinsky et al. already have the features required for maintaining stent length upon expansion, and state that additional improvements are needed with regard to flexibility and scaffolding, one of ordinary skill in the art would not look to Burgermeister for any disclosure regarding methods of maintaining the stent length on expansion of the stent.

Moreover, the Wolinsky patent emphasizes the use of 'links' which extend from inflection points to connect adjacent rings. As described in the patent:

> the rings 20a-c are provided with inflection points 21 on some portions of the rings 20a-c which extend between an adjacent peak 22 and valley 23 of the rings 20a-c. At each inflection point 21, a portion of the ring extends in a generally circumferential direction (indicated generally 24) for a short distance…The inflection point 21 is shown substantially centered between a peak 22 and a valley 23 of the rings 20a-c. A link 25 is joined at one end at the inflection point 21 a on one ring 20a and also joined at a second end at a second inflection point 21b on an adjacent ring 20b. This link 25 joins the rings 20a-b together. (col. 6, lines 15-26)

The purpose of links extending from the inflection points between the peaks and the valleys is apparent from the following passage in Wolinksy (col. 4, lines 43-50):

> As stents are advanced through tortuosities of a vessel, they are subjected to bending forces which can produce longitudinal stresses on the connector links. If the movement of connector links pulls the undulations open from their crimped position, the stent can become radially enlarged and have difficulty in crossing a narrow lesion. *The present invention reduces the potential for this problem by aligning the connection of the links with the rings at a short, circumferentially extending portion, by providing curvature in the links which are then able to flex and thereby reduce stress on the junctions between the rings and the links and by providing "dead end" connections with the links which then avoids the transmission of forces from ring to ring throughout the length of the stent. (emphasis added)*

In light of this teaching, one of ordinary skill in the art would not reposition the Wolinsky connectors and replace them with Burgermeister connectors because it would defeat the purpose of the Wolinsky patent and would change the principal of operation of the Wolinsky device. See, for example, MPEP section § 2143.01 V, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959), which states that the proposed modification cannot change the principle of operation of a reference.

According to KSR, one of ordinary skill in the art must not only be able to make the predictable variation to the device, they must also be able to see the benefit in doing so. If such a benefit cannot be seen, the combination does not preclude patentability under 35 U.S.C. §103(a). See *KSR InternationalCo. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007).

As one of ordinary skill in the art would not look to the Burgermeister reference to modify the Wolinsky et al. stent because the stent already has connectors that maintain the overall stent length before and after expansion, the combination fails to render claim 1 or claim 26 obvious. Combining the cover of Erbel et al. with Wolinsky et al. fails to suggest a medical device with such connectors as recited in claim 1.

Furthermore, even if the combination were made, it fails to suggest a plurality of interconnected struts having curved regions which curve about the first region of the special strut and a plurality of interconnected struts adjacent the second side of the special strut, the interconnected struts having curved regions which curve about the second region of the special strut for the purpose of improved crimpability.

As discussed above in Section I, Erbel is silent as to the issue of special struts and the location of markers within a band.

Moreover, as discussed above in Section I, Erbel does not teach or suggest that the markers disposed along the edge of the cover be a part of any 'special' struts of the stent, as is required by the instant claims.

Thus, the proposed combination of references would still not disclose using special struts which include radiopaque markers to mark the ends of the cover.

For at least these reasons, independent claims 1 and 26 are not obvious over this combination.

Claims 2, 4, 5, 7-10, 15, 34 and 35 depend from claim 1 and claim 27 depends from claim 26 and claim 27 and are not obvious over this combination for at least the reasons that claims 1 and 26 are not obvious over this combination.

III. The examiner erred in rejecting claim 6 under 35 U.S.C. §103(a) as being obvious over Wolinsky in view of Burgermeister and further in view of Erbel et al., and further in view of Barone (USPN 6,613,078).

Claim 6 depends from claim 1. Claim 1 is not obvious over the combination of Wolinsky et al., Burgermeister and Erbel et al. as discussed above. The combination would not be made because the Wolinsky et al. stent already has connectors that maintain the overall stent length before and after expansion, and even if the combination were made, it fails to disclose or suggest a plurality of interconnected struts adjacent the first side of the special strut having curved regions which curve about the first region of the special strut and a plurality of interconnected struts adjacent the second side of the special strut, the interconnected struts having curved regions which curve about the second region of the special strut for the purpose of improving stent crimpability.

Combining Barone which, it is asserted in the Final Office Action mailed

11/14/2007, discloses a stent with two covers, fails to render claim 1 obvious because Wolinksy et al. and Burgermeister would not be combined, and even if they were, the combination still fails to disclose or suggest a plurality of interconnected struts having curved regions which curve about the first region and a plurality of interconnected struts adjacent the second side of the special strut, the interconnected struts having curved regions which curve about the second region of the special strut for the purpose of improved crimpability.

Moreover, as discussed above, Erbel is silent as to the issue of special struts and the location of markers within a band. Also, Erbel does not teach or suggest that the markers disposed along the edge of the cover be a part of any 'special' struts of the stent, as is required by the instant claims.

Claim 6 is not obvious over this combination for at least the reasons that claim 1 is not obvious.

IV. The examiner erred in rejecting claim 6 under 35 U.S.C. 103(a) as being unpatentable over Cox et al. in view of Garrison et al. and further in view of Erbel as applied to claim I above, and further in view of Barone (USPN 6,613,078).

Claim 6 depends from claim 1. Claim 1 has been discussed above and is not obvious over Cox et al., Garrison et al. and Erbel et al. because the combination fails to disclose or suggest the special strut recited in claim 1 and further fails to disclose the radiopaque markers within special struts being used to mark the ends of a cover.

Furthermore, the combination fails to disclose or suggest a plurality of interconnected struts adjacent the first side of the special strut having curved regions which curve about the first region of the special strut and a plurality of interconnected struts adjacent the second side of the special strut, the interconnected struts having curved regions which curve

about the second region of the special strut for the purpose of improving stent crimpability.

Combining the two stent covers of Barone, as asserted in the Office Action, with Cox et al., Garrison et al. and Erbel et al. fails to render claim 1 patentable because the combination fails to provide features of claim 1, including the special strut as recited therein as well as the use of the radiopaque markers with special struts for marking the ends of a cover.

Claim 6 is patentable over this combination for at least the reasons that claim 1 is patentable over this combination.

V. The examiner erred in rejecting claims 13 and 14 under 35 U.S.C. 103(a) as being obvious over Cox in view of Garrison and further in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

Claims 13 and 14 depend from claim 1.

Claim 1 has been discussed above and is patentable over Cox et al. in view of Garrison et al. and further in view of Erbel et al. for the reasons provided above.

Furthermore, the combination fails to disclose or suggest a plurality of interconnected struts adjacent the first side of the special strut having curved regions which curve about the first region of the special strut and a plurality of interconnected struts adjacent the second side of the special strut, the interconnected struts having curved regions which curve about the second region of the special strut for the purpose of improving stent crimpability

Combining plating, painting, pressing, sawing or welding with this combination of references still fails to provide the special strut recited in claim 1 and likewise fails to provide for the use of the radiopaque markers with special struts for marking the ends of a cover.

Therefore, claims 13 and 14 are patentable over this combination for at least the reasons that claim 1 is patentable over this combination.

VI. Whether the examiner erred in rejecting claims 13 and 14 under 35 U.S.C. 103(a) as being obvious over Wolinsky in view of Burgermeister and further in view of Erbel as applied to claim I above, and further in view of admitted prior art (admission).

Claims 13 and 14 depend from claim 1.

Claim 1 is not obvious over Wolinsky et al. in view of Burgermeister and further in view of Erbel et al. for at least the reasons as discussed above.

Combining plating, painting, pressing, sawing or welding with this combination of references as asserted in the Final Office Action mailed 11/14/2007 still fails to provide the special strut recited in claim 1 and likewise fails to provide for the use of the radiopaque markers with special struts for marking the ends of a cover.

Claims 13 and 14 are patentable over this combination for at least the reasons that claim 1 is patentable over this combination.

CONCLUSION

Based on the foregoing, claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are not obvious over Cox et al. (USPN 6,652,579) in view of Garrison et al. (USPN 6,520,984) and further in view of Erbel et al. (US 2004/0116998).

Reversal of the rejection is respectfully requested.

Based on the foregoing, claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are not obvious over Wolinsky (USPN 6,730,116) in view of Burgermeister (USPN 6,790,227) and further in view of Erbel et al. (US Pub 200410116998).

Reversal of the rejection is respectfully requested.

Based on the foregoing, claim 6 is not obvious over Wolinsky in view of Burgermeister and further in view of Erbel et al., and further in view of Barone (USPN 6,613,078).

Based on the foregoing, claim 6 is not obvious over Cox et al. in view of Garrison et al. and further in view of Erbel et al. as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

Reversal of the rejections of claim 6 is respectfully requested

Based on the foregoing, claims 13 and 14 are not obvious over Cox in view of Garrison and further in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

Based on the foregoing, claims 13 and 14 are not obvious over Wolinsky in view of Burgermeister and further in view of Erbel as applied to claim I above, and further in view of admitted prior art (admission).

Reversal of the rejections of claims 13 and 14 is respectfully requested.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 2, 2008

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viii. Claims appendix

Claim 1. A medical device having a longitudinal axis, the device comprising:

a first serpentine band and a second serpentine band adjacent thereto, each serpentine band formed of interconnected struts and having a distal end and a proximal end, each strut extending between a peak at the distal end of the serpentine band and a trough at the proximal end of the serpentine band,

at least one of the struts being a special strut, each special strut having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region, the first region curving in a direction opposite to the second region relative to the longitudinal axis of the device, each special strut having a radiopaque marker between the first and second regions, each special strut having a plurality of interconnected struts adjacent the first side, the interconnected struts having curved regions which curve about the first region and a plurality of interconnected struts adjacent the second side, the interconnected struts having curved regions which curve about the second region,

the first serpentine band connected to the second serpentine band by a connector which extends from one of the ends of the first serpentine band to one of the ends of the second serpentine band,

at least one cover, the at least one cover on at least one region of the medical device, a plurality of the radiopaque markers marking the proximal end of the at least one region and a plurality of the radiopaque markers marking the distal end of the at least one region.

Claim 2. The medical device of claim 1 wherein the special struts are in a region between the ends of the medical device.

Claim 4. The medical device of claim 1 wherein the cover extends about the circumference of the medical device.

Claim 5. The medical device of claim 1 wherein the cover does not cover the entirety of the medical device.

Claim 6. The medical device of claim 1 comprising a second cover covering a second region of the stent, another portion of the special struts located at the periphery of the second region of the stent.

Claim 7. The medical device of claim 1 wherein a cover extends about the medical device in the region of each special strut.

Claim 8. The medical device of claim 2 wherein the special struts are located anywhere between the middle of the medical device and a position one half of the way from the middle of the medical device to an end of the medical device.

Claim 9. The medical device of claim 1 wherein some of the special struts are at one end of the medical device.

Claim 10. The medical device of claim 1 wherein one of the special struts is at one end of the medical device and another special strut is at the other end of the medical device.

Claim 13. The medical device of claim 1 wherein the radiopaque markers are in the form of plated radiopaque material, coated radiopaque material, or painted radiopaque material.

Claim 14. The medical device of claim 1 wherein the radiopaque markers are in the form of swaged radiopaque material or welded radiopaque material.

Claim 15. The medical device of claim 1 in the form of a stent.

Claims 26. A stent in an unexpanded state comprising:

a plurality of serpentine bands, each serpentine band having a distal end having a

peak and a proximal end having a trough and formed of interconnected struts having a first side and a second side, the plurality of serpentine bands including a proximal-most serpentine band and a distal-most serpentine band and a plurality of intermediate serpentine bands between the proximal-most and distal-most serpentine bands, some of the intermediate serpentine bands including interconnected struts which are special struts, each special strut extending from the peak of the serpentine band to the trough of the serpentine band and having a radiopaque marker therebetween the first side and second side; circumferentially adjacent each side of each special strut are a plurality of interconnected struts, the first side and the second side of each interconnected strut of the plurality having a curved region which curves about the radiopaque marker;

a first serpentine band and a second serpentine band being immediately adjacent one another and connected by a connector extending from the distal end of the first serpentine band to the proximal end of the second serpentine band,

at least one cover, the at least one cover on at least one region of the medical device, a plurality of the special struts located at one end of the cover and another plurality of the special struts located at another end of the cover to mark the location of the cover.

Claim 27. The stent of claim 26 wherein the special struts are not at an end of the stent.

Claim 28. The stent of claim 26 wherein the radiopaque markers are bulbous.

Claim 34. The stent of claim 1 wherein the cover does not extends about an entire circumference of the stent.

Claim 35. The stent of claim 34 where the cover does not extend over the entire length of the stent.

(ix) Related Proceedings Appendix

N/A

(x) Evidence Appendix

None